

**REMARKS**

Applicants acknowledge receipt of an Office Action dated October 9, 2001.

In this response, Applicants have amended claims 1-3 and 18. Entry of the amendment is respectfully requested because, at a minimum, it is believed to reduce the number of issues for appeal. Following entry of these amendments, claims 1-16 and 18-25 are pending in the application.

In view of the foregoing amendments and the remarks that follow, Applicants respectfully request reconsideration of the present application.

**Rejections Under 35 U.S.C. § 112, 2<sup>nd</sup> Paragraph**

In the Office Action, the PTO has rejected claims 1-17 under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph for the reasons set forth in paragraph 2 of the Office Action dated February 13, 2001.

As an initial matter, Applicants note that all materials are not plastifiable when structurally degraded mechanically, thermally, chemically or otherwise. For example, cellulose is not plastifiable. Upon heating it decomposes, but never becomes plastifiable, not even in the presence of plastifiers such as glycerol. The same is true for many other natural or synthetic materials. Collagen is also not plastifiable". Aqueous collagen mixtures are only extrudable under certain carefully chosen conditions, as is shown by Higgins (see below).

In this response, Applicants have amended claims 1-3 and 18 to delete the term "plastifiable". This amendment does not narrow the scope of these claims. From the various process steps recited in present claim 1, in particular step b), it is clear that a thermoplastic mass is formed and hence the starting materials are plastifiable.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the outstanding rejections under § 112, 2<sup>nd</sup> paragraph.

**Rejections Under 35 U.S.C. § 103(a)**

*In the Office Action, the PTO has rejected claims 1-17, 18-23, and 25 under 35 U.S.C. § 103(a) as being unpatentable over Higgins (US 4,154,857) in view of Lim et al. (WO 93/191259).*

The PTO has asserted that Higgins discloses a composition of collagen and polysaccharide, which is extruded into tubular structures (film tubes). This is, in fact, not what the reference teaches. The teaching of Higgins is restricted to collagen

casings which are treated with an aqueous solution of a polysaccharide dewatering agent and which are subsequently dried. The dewatering agent does not contribute to the mechanical stability and is not even permanently linked with the casing. Accordingly, Higgins discloses in col. 2, lines 47-52, that the bath containing the dewatering agent should also contain the plasticizing agent (glycerol), otherwise the dewatering agent is leached out.

Furthermore, the collagen mass taught by Higgins is not a thermoplastic mass as recited in the present claim 1. Collagen is most frequently prepared from limed animal hide splits which are chopped into pieces and treated with an aqueous acidic swelling agent (see col. 3, lines 19-37, of Higgins). It is common practice to mix the acid-swollen chips with an aqueous fibrous dispersion, wherein the fibers may be wood fibers, cotton, rayon or other cellulosic fibers, or non-cellulosic fibers, such as polyester or polyamide fibers (col. 3, lines 48-53). Higgins teaches that the temperature of the collagen mass must be kept low, i.e., below 25 °C (col. 4, 1.9 - 12). The cold aqueous mass is then extruded under very gentle conditions to form a continuous collagen tube. In a subsequent step the collagen tube is then dewatered and plasticized (normally with glycerol). Higgins clearly does not disclose or even contemplate polysaccharides such as the starch of Lim as part of the aqueous collagen extrusion mass.

In contrast, the presently claimed film is based on biopolymers, in particular on polysaccharides, such as starch, or biopolymers such as protein or carrageenan. The biopolymers form an integral part of the film and cannot be removed from it without destroying the casing. There is no leaching observed when the film is put in a water bath.

Lim et al. teaches a thermoplastic composition which comprises a mixture of starch and protein which are crosslinked with an aldehyde or epoxide crosslinking agent. The protein may be chosen among a variety of substances, collagen being one of them (page 6, first full paragraph).

The PTO has taken the position that *"it would have been obvious to one of ordinary skill in the art to have used the teachings of Lim et al, in the invention of Higgins in order to obtain an edible food casing with good mold release and increased water-resistance"*. However, even if a lubricant and a crosslinker as taught by Lim were added to the collagen mass of Higgins, this would still not result in an edible shaped

body as recited in present claim 1. A person skilled in the art would never have, been motivated to make such a combination, since the additional components would be washed away in the various water baths and therefore could not perform their intended function. Furthermore, since the collagen casings of Higgins are produced without a mold, a "good mold release" is not an issue. Applicants further note that collagen is not suitable for the purposes of the present invention (see specification, page 4, line 11).

As discussed above, Higgins is directed to an improved method of producing collagen products, namely an improved dewatering process. Higgins explicitly requires collagen, and one skilled in the art seeking to modify Higgins would have no motivation to remove the collagen as proposed by the PTO, because to do so would render Higgins unsatisfactory for its intended purpose. That is, removing the collagen from the casings of Higgins would render Higgins' improved process of producing collagen products moot. Furthermore, even if a lubricant and a crosslinker as taught by Lim were added to the collagen mass of Higgins, this would still not result in an edible shaped body as recited in present claim 1. A person skilled in the art would never have made such a combination, since the additional components would be washed away in the various water baths and therefore could not perform their intended function. See MPEP §2143.02 ("THE PROPOSED MODIFICATION CANNOT RENDER THE PRIOR ART UNSATISFACTORY FOR ITS INTENDED PURPOSE"). Thus, one skilled in the art, considering the prior art as a whole, would not have been motivated to combine the teachings of Higgins and Lim et al.

*In the Office Action, the PTO has rejected of claims 14 - 16, and 24 under 35 U.S.C. § 103(a) as being unpatentable over Higgins in view of Lim et al. and Metzger (US 5,681,517).*

As already emphasized previously, Metzger does not cure the deficiencies of Higgins or Lim et al. All Metzger teaches is a method for producing a flat or tubular film based on casein (col. 2, lines 22 - 46). The film may be an edible sausage casing (col. 4, lines 23/24). However, since, as set forth above, a person of ordinary skill in the art would not have combined the teaching of Higgins with that of Lim et al., the combination with the additional secondary reference also cannot render obvious the subject matter of present claims 14 to 16 and 24,

USSN 09/355,637  
Attorney Docket No. 051009-0122

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the outstanding rejections under §103.

### CONCLUSION

In view of the foregoing amendments and remarks, applicants respectfully submit that all of the pending claims are now in condition for allowance. An early notice to this effect is earnestly solicited. If there are any questions regarding the application, the Examiner is invited to contact the undersigned at the number below.

Respectfully submitted,

Date April 9, 2002

FOLEY & LARDNER  
Customer Number: 22428



22428

PATENT TRADEMARK OFFICE  
Telephone: (202) 672-5300  
Facsimile: (202) 672-5399

By *RL Schwaab* 38,011

for Richard L. Schwaab  
Attorney for Applicant  
Registration No. 25,479

Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 19-0741 for any such fees; and applicant(s) hereby petition for any needed extension of time.

**Versions with Markings to Show Changes Made**

**In the Claims:**

1. (Twice Amended) An edible shaped body in the form of a flat or tubular fiber containing film based on [plastifiable] biopolymers or cleavage products or derivatives thereof and/or synthetic polymers of natural monomers is produced by a process having the following stages:

- a) mixing the biopolymers, cleavage products or derivatives thereof and/or the synthetic polymers with at least one edible plasticizer, at least one lubricant and at least one crosslinker and fibers,
- b) melting the resultant mixture to give a thermoplastic mass,
- c) extruding this mass and
- d) calendering and/or stretching or blowing the product obtained from the extrusion to give the edible shaped body.

2. (Amended) The shaped body as claimed in claim 1, wherein the [plastifiable] biopolymer, the [likewise plastifiable] cleavage products produced therefrom and/or the [plastifiable] synthetic polymer is thermoplastic starch, a starch derivative, an extrudable natural protein, casein or a casein derivate, chitin, chitosan, alginic acid, alginate, carrageenan, dextran, galactomannan, pectin or polylactic acid.

3. (Twice Amended) The shaped body as claimed in claim 1, wherein the content of [plastifiable] biopolymer, cleavage products and derivatives thereof and synthetic polymers of natural monomers is from 10 to 90% by weight, based on the total weight of the shaped body.

18. (Amended) The shaped body as claimed in claim 1, wherein the content of [plastifiable] biopolymer, cleavage products and derivatives thereof and synthetic polymers of natural monomers is from 15 to 80% by weight, based on the total weight of the shaped body.